DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 10, 2014

Spineology, Incorporated
Mr. Tim Crabtree
Regulatory Affairs Manager
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K142213
Trade/Device Name: VIA™ Spinous Process Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: August 7, 2014
Received: August 12, 2014

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142213

Device Name
VIA™ Spinous Process Fixation System

Indications for Use *(Describe)*

The VIA™ Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 - Sl). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Trauma (i.e., fracture or dislocation)
- Spondylolisthesis
- Tumor

The VIA™ Spinous Process Fixation System is not intended for stand-alone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. SUBMITTER

Spineology Inc.
7800 3rd Street N.
Saint Paul, MN 55128

Contact Person: Tim Crabtree
Phone: 651.256.8534
Fax: 651.256.8505

Date Prepared: September 9, 2014

II. DEVICE

Device Name: VIA™ Spinous Process Fixation System
Common Name**:** Spinous Process Plate
Regulation: 21 CFR §888.3050-Spinal Interlaminal Fixation Orthosis.
Regulatory Class: II
Product Code: PEK

III. PREDICATE DEVICE

Spineology Spinous Process Fixation System (K123232)

IV. PURPOSE

The purpose of this submission is to provide notification for the addition of plates with a modified spike design to the system.

V. DEVICE DESCRIPTION

The VIA™ Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for single level plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion, and it is not intended for stand-alone use. When the VIA™ Spinous Process Fixation System is used as supplemental fixation in interbody fusion procedures, its use is limited to the treatment of degenerative disc disease (DDD) of the lumbosacral spine (L2-S1). The VIA Spinous Process Fixation System consists of a three-piece design. The larger male piece (plate) is comprised of a plate with teeth and a spacer in the middle. The two other additional pieces are plates (with teeth) that contain the female ends of the connection with the male spacer. The two female plates engage with the larger plate independently to accommodate variations in the spinal anatomy. The components are locked together with a set screw after assembly. The spinous

process contact areas (with the teeth sections) on both the male and female plates do not vary in size. The central spacer on the male plate varies in height (cephalo-caudad), thus providing the different sizes of the device. All components are composed of titanium alloy (Ti-6Al-4V-ELI ASTM F136). Associated accessories include surgical instruments to facilitate implantation.

VI. INDICATIONS FOR USE

The VIA™ Spinous Process Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-Sl). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions:

- Degenerative disc disease - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Trauma (i.e., fracture or dislocation)
- Spondylolisthesis
- Tumor

The VIA™ Spinous Process Fixation System is not intended for stand-alone use.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The VIA™ Spinous Process Fixation System shares the same materials, features, intended use, manufacturing, and technological characteristics as the Spineology Spinous Process Plate.

VIII. PERFORMANCE DATA

The following verification tests were performed:

- Insertion Testing
- Grip Strength Testing (using a modified ASTM F543-13 setup)
- Dynamic Compression Bending (per ASTM F1717-13)

The results met applicable acceptance criteria and verified the design features.

IX. CONCLUSIONS

The VIA™ Spinous Process Fixation System is substantially equivalent to the predicate device, the Spineology Spinous Process Fixation System (K123232). The information presented in this premarket notification demonstrates that the materials, technological characteristics, and the intended use are the same.